

REMARKS

Claims 1-27 are pending in the application. Of these claims, claims 1-14 are subject to examination. Non-elected claims 15-27 depend from claim 1 and incorporate all limitations of an elected claim, and rejoinder has been requested.

In this response, claims 1 and 12 are currently amended, and claims 10 and 11 have been canceled. No new claims have been added. Applicant respectfully requests reconsideration of the claims in view of the above amendments and the following remarks.

Telephone Interview

Applicants acknowledge with appreciation the courtesy of a telephone interview on January 9, 2009, between Examiner Purdy, SPE Blanchard, and Applicant's Attorney Leslie Meyer-Leon, to discuss the Office Action of December 8, 2008.

Amendments to the Claims

Claim 1 has been amended to include the features of claims 10 and 11, with claims 10 and 11 being cancelled, and claim 12 amended to depend from claim 1. Amended claim 1 is therefore directed to a tablet in which both core and mantle dissolve rapidly in the stomach and, apart from the sumatriptan in the core, the rapid release mantle and the core are composed of substantially the same materials. Support for the amendment to claim 1 is found in the claims as originally filed, and in the specification at, e.g., page 7, lines 22-23.

Dandiker Reference

Applicants further acknowledge with appreciation that the prior rejection under §102(b) over Dandiker et al., and the two §103(a) rejections over Dandiker in view of Lerner et al. and Lieberman et al., respectively, have been withdrawn. By withdrawing these rejections, the Examiner has advanced prosecution by establishing on the record that "***Dandiker et al. does not disclose Applicants rapid release mantle free of sumatriptan.***" See, Office Action, repeated at each of paragraphs 4, 5, and 6.

Applicants wish to correct a mistake at page 4 of the Office Action (*stating*, "For clarity, Example 10 is pasted below"). The text appearing below the heading "**Core and Coating**" does not appear anywhere in Dandiker, and in fact impermissibly re-writes

Dandiker. To correct the record, Applicant has pasted verbatim Dandiker's Example 10 as follows:

15 EXAMPLE 10  
Tables for immediate release and pulsatile release

Tablets Core		% w/w
20	Sumatriptan (as succinate)	50
	Microcrystalline cellulose	23
	Lactose	23
	Polyvinylpyrrolidone	2
	Sodium stearyl fumerate	2
25	* Imprégne Alsthal	qs.

\* not present in the final product.

Sumatriptan was dry mixed with microcrystalline cellulose and lactose and the mixture was granulated using a granulating fluid composed of polyvinylpyrrolidone dissolved in isopropyl alcohol. The granulate was dried in a fluid bed drier, sieved and blended with sodium stearyl fumerate before compression on a suitable tablets press to produce 100 mg core tablets containing 50 mg of sumatriptan (as succinate) which were 3.5 mm in diameter and 3.0 mm in thickness.

Intermediate Polymer Layer		% w/w
40	* Hydroxypropyl Methylcellulose	55
	Microcrystalline Cellulose	20
	Dibasic calcium phosphate	23
	Colloidal silicon dioxide	1
	Sodium stearyl fumerate	1

\* swell capacity 25% in water ~ 300 cps.

45 The excipients for the intermediate layer were dry mixed and the core tablet was compression coated using the resulting blend to produce 230 mg tablets, 8.7 mm in diameter and 4.0 mm in thickness.

Outer Sumatriptan Layer

50 Same formulation as the core tablet.

The compression coated tablets were further coated with 160 mg of the tablet core blend by compression.

55 The release of the drug was monitored using dissolution equipment which conforms to the requirements of the USP, in which 900 ml of simulated gastric fluid was maintained at 37° C. and used as the dissolution medium. The USP I dissolution method was used at a rotation speed of 250 rpm.

Initial immediate release of sumatriptan was obtained followed by pulsatile release of the drug after a period of about 1.5 hours.

60 The core tablets described above were also coated with the above intermediate polymer blend to give tablets of 11.0 mm in diameter which were further coated with the outer sumatriptan layer blend (100 mg). The resulting tablets (720 mg) gave initial immediate release of sumatriptan followed by pulsatile release of the drug after a period of 3 hours.

Rejection under 35 U.S.C. § 103(a)

Claims 1-14 have been rejected under 35 U.S.C. § 103(a) as not being patentable over Dandiker et al. (US 5,425,950) in view of Holt et al. (US 6,740,341, filed 11/24/1999; hereafter “Holt et al.”) and meds.com (<http://www.meds.com/conrad/aash/guterman.html>, Sept 1997), which is an on-line newsletter article (“Treatment of Migraine Headache: Sumatriptan (SUMA) (hereafter “Meds.com”). The rejection is respectfully traversed.

Dandiker relates to tablets that are designed for delayed release or pulsed release of medication, achieved by using a multi-layer tablet, each layer delaying the release of drug from the next. As we have submitted before, this is achieved using a tablet consisting of at least three layers (i.e. inner layer(s), outer layer(s) and an outer coating). This tablet construction can clearly be seen e.g. at column 7, lines 3-4 of Dandiker, which relates to the concentration of active ingredient in the inner or outer layers or outer coating.

The tablet of Example 10 that the Examiner uses as a starting point for his rejection based on obviousness has a core and outer coating that contains sumatriptan, which are separated by an intermediate polymer layer, which erodes gradually, delaying release of active from the tablet core. Indeed, the intermediate layer (layer II) of Dandiker is never rapid release and thus would always delay release. This produced a tablet that released sumatriptan immediately from the outer coating, but the release of active from the core occurred after 1.5 or 3 hours, depending on the formulation. This release profile is in line with the stated aim of Dandiker to produce a tablet with delayed or pulsed release characteristics, but inconsistent with the aims of the present invention to provide a tablet with rapid release properties. As such, it would not be obvious for a person skilled in the art to look to Dandiker or similar patents for a starting point for the development of tablets for the rapid release of medication.

Holt relates to a tablet that contains three layers: a drug-containing core, a spacing layer, and a taste-masking outer layer. Holt discloses that the spacing layer is present to separate the drug-containing core and the taste-masking layer to avoid the active interfering with the taste-masking layer (Holt, column 2, lines 59-63). Holt therefore teaches against the use of a taste-masking tablet in which these layers can come into

contact, such as in an embodiment of the present patent application. Moreover, each layer of the Holt tablet appears to have a different formulation (e.g. Holt; Example 2), and as such it is a more complex and costly formulation than the tablet of the present invention. The skilled person would therefore not seek the teachings of Holt to assist in the development of the present tablet.

In the unlikely event that the skilled person were to apply the teachings of Dandiker in view of Holt and the cited Meds.com excerpt, as alleged by the Examiner, he would not arrive at the claimed invention. In particular, Holt advocates the use of three layers each having a different composition (see Examples of Holt) and thus following the teaching of Holt would not lead the skilled person to provide a tablet as claimed in which core and mantle are composed of substantially the same materials. We would add that the cited Meds.com excerpt adds nothing to the Examiner's argument — the unpleasant taste of sumatriptan is mentioned in the present specification.

#### CONCLUSION

All claims are believed to be in a form suitable for allowance and allowance is respectfully requested. The Applicant further requests that the Examiner contact the undersigned, Leslie Meyer-Leon, if it will assist further examination of this application.

Applicant does not believe any extension of time is required for timely consideration of this response. In the event that an extension has been overlooked, this conditional petition of extension is hereby submitted. Applicant requests that deposit account number 19-4972 be charged for any fees that may be required for the timely consideration of this application.

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Respectfully submitted,



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